MENTOR
Automation Technology

June 17, 2002

K011493

OCT 01 2002

Subject: 510(k) Summary of Safety and Effectiveness Information for the Mentor Isoloader Automatic Needle Loading System and Physics Workstation for Brachytherapy

Contact:	George Hoedeman, Division President
Proprietary:	Mentor Isoloader Automatic Needle Loading System and Physics Workstation for Brachytherapy
Common:	Radionuclide Dose Calibrator Remote-Controlled Radionuclide Applicator System (Accessory to)
Classification:	90KPT – Class II – 21CFR §892.1360 90JAQ – Class II – 21CFR §892.5700

The 510(k) summary of safety and effectiveness information is submitted in accordance with the requirements of SMDA 1990 and 1992.

Substantially Equivalent Devices

The Mentor Isoloader Automatic Needle Loading System and Physics Workstation for Brachytherapy is substantially equivalent in intended use to the following currently marketed device(s):

- Standard Imaging HDR 1000 Plus Ion Chamber
- Nucletron Corporation seedSelectron

Primary Functions

The Mentor Isoloader™ Automatic Needle Loading System and Physics Workstation for Brachytherapy is a computer-based workstation that has three primary functions:

- The Isoloader is a dose calibrator that assays I-125 and Pd-103 radionuclide seeds and verifies that the measured strength is within a user-specified deviation from the strength ordered for the procedure;
- The Isoloader automatically loads sterile needles with sterilized radionuclide seeds and spacers from the preloaded and sterilized IsoCartridge based on a dose plan that is either input manually or imported from a compatible prostate brachytherapy treatment planning system; and
- The Isoloader is also able to generate a series of reports based on data captured during the procedure including case summary and reimbursement reports.

The Isoloader is not intended for use within an MRI environment.

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Indications for Use

The Mentor Isoloader Automatic Needle Loading System and Physics Workstation for Brachytherapy is a dose calibrator intended to assay I-125 and Pd-103 radionuclide seeds prior to their administration to patients.

Additionally, the Isoloader is an accessory to a manual/remote radionuclide applicator system that provides an automatic needle loading feature for loading sterile I-125 or Pd-103 radionuclide seeds and synthetic bio-absorbable spacers into sterile brachytherapy needles prior to their administration to patients.

The Isoloader also provides a report generation feature.

The IsoCartridge component of the Isoloader is a shielded packaging and delivery system provided to the user loaded with I-125 or Pd-103 radionuclide seeds and synthetic bio-absorbable spacers. The loaded IsoCartridge is provided sterile to the user.

Applicable Standards and Guidelines

The Mentor Isoloader™ Automatic Needle Loading System and Physics Workstation for Brachytherapy is designed to comply with the applicable portion of the following standards and guidelines:

1. Guidance for the Submission of Premarket Notifications for Radionuclide Dose Calibrators, Issued 20 Nov 98, FDA
2. Off-The-Shelf Software Use in Medical Devices, Issued on 09 Sep 99, FDA
3. Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices, Issued 29 May 98, FDA
4. General Principles of Software Validation, Final Guidance for Industry and FDA Staff, Issued 11 Jan 02, FDA.
5. UL 94 Underwriters Laboratory-Standard Tests for Flammability of Plastic Materials
6. UL 2601-1 PART 1: General Requirements For Safety, Medical Electrical Equipment
7. CSA C22.2 #601: General Requirements For Safety, Medical Electrical Equipment
8. EN 980 Graphical symbols for use in the labeling of medical devices
9. EN 1041 Medical devices – Information supplied by the manufacturer with medical devices
10. EN ISO 14971:2000, Medical Devices – Application of risk management to medical devices.
11. EN1707 Conical fittings with a 6% (luer) taper for syringes, needles and certain other medical equipment – lock fittings
12. IEC 601-1 (EN 60601-1) International Electrotechnical Commission, Medical Electrical Equipment, Part 1: General Requirements for Safety and Amendments 1 and 2
13. IEC 601-1-1 (EN 60601-1) General Requirements for Safety, 1. Collateral Standard: Safety Requirements for Medical Electrical Systems
14. IEC 601-1-2 (EN 60601-1-2) General Requirements for Safety, 2. Collateral Standard: Electromagnetic Compatibility
15. EN 980-A1 Graphical Symbols for Use in the Labeling Of Medical Devices
16. ISTA Procedure 2A Performance Testing
17. IEEE Std 1074-1991 - Standard for Developing Software Life Cycle Processes.
18. IEC 60601-1-4: 2000 (EN 60601-1-4), Medical electrical equipment – Part 104: General requirements for safety – Collateral Standard: Programmable electrical medical systems.

19. IEC 61303: 1994, Medical electrical equipment – Radionuclide calibrators – Particular methods for describing performance.

The Mentor Isoloader™ Automatic Needle Loading System and Physics Workstation for Brachytherapy was validated through rigorous testing that, in part, support the compliance of the Mentor Isoloader™ Automatic Needle Loading System and Physics Workstation for Brachytherapy to the above mentioned standards.

Additionally, the software for the Mentor Isoloader™ Automatic Needle Loading System and Physics Workstation for Brachytherapy was developed following a robust software development life cycle process and was fully specified and validated by Mentor Automation Technology.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 01 2002

Mr. George M. Hoedeman
President
Mentor Automation Technology
9727 Valley View Road
EDEN PRAIRIE MN 55344

Re: K011493
Trade/Device Name: Mentor Isoloader Automatic Needle Loading System and Physics Workstation for Brachytherapy
Regulation Number: 21 CFR §892.1360
Regulation Name: Radionuclide dose calibrator
Regulatory Class: II
Product Code: 90 KPT
Dated: September 17, 2002
Received: September 18, 2002

Dear Mr. Hoedeman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K011493

Device Name: Mentor Isoloader Automatic Needle Loading System and Physics Workstation for Brachytherapy

Indications for Use:

The Mentor Isoloader Automatic Needle Loading System and Physics Workstation for Brachytherapy is a dose calibrator intended to assay I-125 and Pd-103 radionuclide seeds prior to their administration to patients.

Additionally, the Isoloader is an accessory to a remote radionuclide applicator system that provides an automatic needle loading feature for loading sterile I-125 or Pd-103 radionuclide seeds and synthetic bio-absorbable spacers into sterile brachytherapy needles prior to their administration to patients.

The Isoloader also provides a report generation feature.

The IsoCartridge component of the Isoloader is a shielded packaging and delivery system provided to the user loaded with I-125 or Pd-103 radionuclide seeds and synthetic bio-absorbable spacers. The loaded IsoCartridge is provided sterile to the user.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Radiology

510(k) Number: K011493

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K011493

Prescription Use ✓ OR Over-The-Counter Use
(Per 21CFR801.109)